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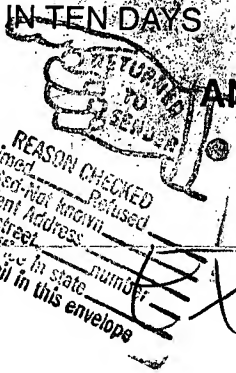

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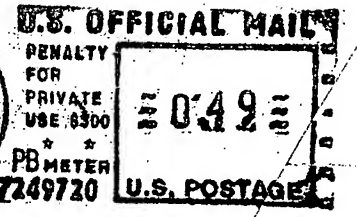

7590 12/31/2003

DELTAGEN, INC.
740 Bay Road
Redwood City, CA 94063

For

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,983	11/07/2001	Keith D. Allen	R-517	9383

7590 12/31/2003

DELTAGEN, INC.
740 Bay Road
Redwood City, CA 94063

EXAMINER	
QIAN, CELINE X	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,983	ALLEN ET AL.	
	Examiner	Art Unit	
	Celine X Qian	1636	

-- The MAILING DATE of this communication app ars on the cover sheet with th correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,13 and 23-39* is/are pending in the application.

4a) Of the above claim(s) *11,13,23 and 24* is/are withdrawn from consideration.

5)☒ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *7/24/02* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 11, 13, 23, 24, 25-39 are pending in the application. Claims 11, 13, 23 and 24 are withdrawn from consideration for being directed to non-elected subject matter. Claims 25-39 are currently under examination.

This Office Action is in response to the Amendment filed on 9/26/03.

Response to Amendment

The rejection of claims 3-10, 12, 14-22 under 35 U.S.C. 112 1st paragraph is moot in light of Applicant's cancellation of the claims.

The rejection of claims 1, 2, 8, 12, 14 and 21 under 35 U.S.C. 112 2nd paragraph is moot in light of Applicant's cancellation of the claims.

The rejection of claims 1-5 under 35 U.S.C. 102 (a) paragraph is moot in light of Applicant's cancellation of the claims.

Claims 28-39 are rejected under 35 U.S.C. 112 1st paragraph for reasons set forth below.

Claims 31 and 38 are rejected under 35 U.S.C.112 2nd paragraph for reasons set forth below.

Claims 25-27 are rejected under 35 U.S.C. 102 (a) for reasons set forth below.

New Grounds of Rejection Necessitated by Applicant's Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a heterozygous knockout mouse comprising a disruption in one copy of PERK gene which result in non expression of the gene, wherein there is one functional PERK allele that produces functional PERK protein, and exhibiting phenotypic features including increased susceptibility to seizure as compared to wild type mice, a method of producing such a transgenic mouse by homologous recombination in mouse ES cell, and a cell isolated from the knockout mouse, and method of using said mouse to screen an agent that ameliorates a phenotype of said mouse, does not reasonably provide enablement for other transgenic and/or knockout mouse comprising a heterozygous disruption in the PERK gene, wherein the functional allele do not express a functional PERK protein, and cells isolated from said mouse. Further, the specification is not enabling for a transgenic mouse having homozygous disruption in the PERK gene wherein said mouse exhibits increased incidence of lethality during perinatal development. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claimed invention is enabled to the scope as indicated above for same reasons as applied to the claims 3-10, 12, 14-22 (see previous office action). The present claims are still drawn to both heterozygous and homozygous transgenic mouse comprising a disruption in the endogenous PERK gene. As discussed in the previous office action, the disclosed use for the transgenic mouse is to screen agents that modulate expression or function of the PERK or ameliorate a phenotype of the result from the gene disruption. The specification fails to teach how to use the homozygous knockout mouse to screen for agents that modulate the expression or

function of the PERK. It is unclear how such agents can be screened by using the homozygous knockout mouse since the homozygous mouse does not produce functional PERK gene or protein, and in addition, they are dead within 1-2 days. The specification fails to teach how to screen for agents that ameliorate a phenotype, the increased lethality, of the homozygous mouse. Thus, whether the homozygous mouse can be used to for screening test is unpredictable. Therefore, the specification does not support the enablement of a transgenic mouse with homozygous disruption of the PERK gene.

The specification teaches that the heterozygous PERK knockout mouse exhibits the phenotype of increased susceptibility to seizure. The heterozygous knockout mouse has a functional PERK allele, therefore, produces functional PERK protein. However, the claims recite a heterozygous mouse, wherein "the transgenic mouse comprises one PERK gene allele which does not produce functional PERK protein and exhibits increased susceptibility to seizure." It is unclear why the normal allele does not produce functional PERK protein. In addition, the phenotype of such transgenic mouse is not predictable. Therefore, the specification does not support the enablement of such heterozygous mouse. Thus, the scope of the claims exceeds that is enabled by the instant specification, and one of skilled in the art would have to engage in undue experimentation to make/use the invention to its full scope.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: selecting ES cells that undergo homologous recombination.

The recitation of "pseudopregnant mouse gives birth" renders the claim indefinite because a pseudopregnant mouse cannot give birth.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 25-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Harding et al.(2000, Molecular Cell, Vol. 5, pages 897-904).

The teaching of Harding et al. was discussed in detail in the office action mailed on 4/23/03 (see page 10). The claim limitation of "wherein the disruption, results in...phenotype of increased susceptibility of seizure..." is intended use for the claimed targeting construct, which does not carry patentable weight. In other words, this limitation does not change the structure of the claimed target construct or the embryonic stem cell. Therefore, Harding et al. disclose the instantly claimed invention.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

This application contains claims 11, 13, 23 and 24 drawn to an invention nonelected with traverse in the response filed on 3/17/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER